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| 10/687,054 | 10/15/2003 | James E. Brown | DURE-045 | 7524 |
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| DURECT CORPORATION THOMAS P. MCCracken 2 RESULTS WAY CUPERTINO, CA 95014 | | | EXAMINER MEHTA, BHISMA | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,054

Applicant(s)

BROWN ET AL.

Examiner

Bhisma Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on April 2 2007. These drawings are acceptable except for the objections listed below.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "56" has been used to designate both a tubular segment and a trocar (see line 10 of paragraph [0055] and lines 5 and 7 of paragraph [0058]). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the retaining mechanism and the actuating mechanism located within the lumen of the tubular member must be shown or the feature(s) canceled from the claim(s). It is noted that Applicant indicates on page 12 of the Remarks filed April 2 2007 that element 60 in Figure 2 and element 84 in Figure 3 correspond to retaining mechanisms. However,

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element 60 is identified in the specification as a restraining mechanism and element 84 as an implant retaining member. It is suggest that the specification be amended to specifically use the language of retaining mechanisms to describe these elements. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

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of the following is required: The specification fails to disclose the apparatus having an actuating mechanism located within the lumen of the tubular member and adapted to activate a device to be activated within the lumen when the device is translated within the lumen.

Claim Objections

5. Claims 1-7, 9, and 10 are objected to because of the following informalities: Claim 1 recites the limitation "said device" in line 16. It should be noted that the device has been positively recited. There is insufficient antecedent basis for this limitation in this claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not clearly describe how the activation of the device is accomplished by pulling or turning a portion of the device when present in the apparatus. The specific language of pulling or turning a portion of the device is not

found in the specification with respect to how the activation of the device is activated.

This language is also not noted on page 14 of Applicant's remarks.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (U.S. Patent No. 6,530,875) in view of Antaki et al (U.S. Patent No. 6,270,472). Taylor et al disclose an apparatus having an elongated tubular member (32) with a lumen extending from a proximal end to a distal end, a retaining mechanism (98 or 100) for retaining a device (60), a rod (44) positioned within the lumen and being translatable within the lumen, an actuating mechanism (50) located within the lumen and adapted to activate the device, and a locking mechanism (62) for locking onto the rod. The lumen is adapted to translatably receive the device to be activated. The device (60) is activated by being pushed by the rod. The retaining mechanism (98 or 100) is in the form of a leaf-spring as seen in Figures 4B and 4C. Taylor et al also disclose a kit in the form of the apparatus and drug delivery devices (60). Taylor et al disclose the apparatus substantially as claimed. However, Taylor et al do not disclose a resistive load means positioned in the lumen which is adapted to contact the device in the lumen. Antaki et al teach an elongated tubular member (39) having a

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resistive load means (83, 85) in the form of springs, a rod (47) located proximal to the resistive load means, and a locking mechanism (49) for locking onto the rod. In lines 56-65 of column 9, Antaki et al teach that the resistive load means comprises a first load member (85) and a second load member (83) where the second load member is stronger than the first load member, thus the resistive load level of the second load member is greater than the resistive load level of the first load member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the lumen of Taylor et al with the resistive load means as taught by Antaki et al as both Taylor et al and Antaki et al disclose apparatus to deliver implants into a patient's body and Antaki et al disclose that it is well known to use the resistive load means to deliver an implant into the body. As to claims 5 and 6, Even though Antaki et al teach that the second load member is stronger than the first load member, Antaki is silent on the specific of the resistive loads of the load members and by how much the second load member is stronger than the first load member. The parameters of resistive load are deemed matters of design of choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

10. Applicant's arguments filed April 2 2007 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

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any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Both Taylor et al and Antaki et al disclose apparatus for activating a device where the device is located within a lumen of an elongated tubular member and Antaki et al disclose the specifics of using a resistive load means to contact the device in the lumen. Additionally, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Antaki et al discloses that it is well known to use the resistive load means to contact the obturator (37) which is activated to deliver an implant into a patient's body.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

